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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,069	02/13/2002	Charles Andrianjara	A0000434-01-CFP	7470

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WARNER-LAMBERT COMPANY
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ANN ARBOR, MI 48105

EXAMINER

MCKENZIE, THOMAS C

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 06/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/075,069

Applicant(s)

ANDRIANJARA ET AL.

Examiner

Thomas McKenzie Ph.D.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. This action is in response to an application filed on 2/13/02. There are forty-five claims pending. Claims 1-32 are compound claims. Claim 33-35 is a composition claim. Claims 36-45 are use claims. The application concerns some compounds that bind to the enzyme MMP-13, compositions, and uses thereof.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims parts of 1-35, drawn to compounds that bind to MMP-13 which are the thiazolo[3,2-c]pyrimidine compounds found in Table I, page 18-23, classified in class 544, subclass 278.
- II. Claims parts of 1-35, drawn to compounds that bind to MMP-13 which are the amides of isophthalic acid found in Table II, pages 37-40, classified in class 564, subclass 156.
- III. Claims parts of 1-35, drawn to compounds that bind to MMP-13 which are the esters of isophthalic acid found in Table II, pages 37-40, classified in class 560, subclass 85, among others.
- IV. Claims parts of 1-35, drawn to compounds that bind to MMP-13 which are the thieno[2,3-d]pyrimidinedione compounds found in Table III, pages 46-58, classified in class 544, subclass 278.

- V. Claims parts of 1-35, drawn to compounds which bind to MMP-13 which are the quinazolinedione compounds found in Table IVa, pages 64-71, Table IVb, pages 71-78, and Table VII, pages 129-130 classified in class 544, subclass 285.
- VI. Claims parts of 1-35, drawn to compounds which bind to MMP-13 which are the pyrido[2,3-d]pyrimidine compounds found in Table IVa, pages 64-71, Table IVb, pages 71-78, and Table VII, pages 129-130 classified in class 544, subclass 279.
- VII. Claims parts of 1-35, drawn to compounds which bind to MMP-13 which are the triazolo[4,3-a]quinazoline compounds found in Table V, pages 111-115, and Table VII, pages 129-130, classified in class 544, subclass 251.
- VIII. Claims parts of 1-35, drawn to compounds which bind to MMP-13 which are the imidazolo[1,2-a]quinazoline compounds found in Table V, pages 111-115, classified in class 544, subclass 251.
- IX. Claims parts of 1-35, drawn to compounds which bind to MMP-13 which are the benzo[1,2,4]thiadiazines found in Table VI, pages 123-124, classified in class 544, subclass 13.

- X. Claims parts of 1-35, drawn to all other compounds that bind to MMP-13, classified in class 540, subclass 1, among others.
- XI. Claims 36, 37, 39, 40, 42, 43, and 45, drawn to the preparation of a medicament, classified in class 514, subclass 1, among others
- XII. Claims parts of 38, 41, and 44, drawn to treating various arthritic diseases, classified in class 514, subclass 1, among others.
- XIII. Claims parts of 38, 41, and 44, drawn to treating osteoporosis, classified in class 514, subclass 1, among others.
- XIV. Claims parts of 38, 41, and 44, drawn to treating periodontal disease, classified in class 514, subclass 1, among others.
- XV. Claims parts of 38, 41, and 44, drawn to treating IBD, classified in class 514, subclass 1, among others.
- XVI. Claims parts of 38, 41, and 44, drawn to treating psoriasis, classified in class 514, subclass 1, among others.
- XVII. Claims parts of 38, 41, and 44, drawn to treating MS, classified in class 514, subclass 1, among others.
- XVIII. Claims parts of 38, 41, and 44, drawn to treating cardiac insufficiency, classified in class 514, subclass 1, among others.

XIX. Claims parts of 38, 41, and 44, drawn to treating arteriosclerosis, classified in class 514, subclass 1, among others.

XX. Claims parts of 38, 41, and 44, drawn to treating asthma, classified in class 514, subclass 1, among others.

XXI. Claims parts of 38, 41, and 44, drawn to treating COPD, classified in class 514, subclass 1, among others.

XXII. Claims parts of 38, 41, and 44, drawn to treating age related macular degeneration, classified in class 514, subclass 1, among others.

XXIII. Claims parts of 38, 41, and 44, drawn to treating cancer, classified in class 514, subclass 1, among others.

Claims 1-35 link Groups I-X.

Claims 38, 41, and 44 link Groups XII-XXIII.

3. The inventions are distinct, each from the other because of the following reasons: These multiple claimed compounds are chemically non-equivalent and are not art-recognized as sharing the same biological properties. Inventions I-III and V-X have acquired a separate status in the art as shown by their different classification, thus the patent search required for Group I is not co-extensive with that required for Groups II, III, and V-X. The basic names of these heterocyclic compounds differ, thus the literature search for these various species will be

divergent. Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

Although Groups I and IV are classified together, the core rings are chemically non-equivalent and are not art-recognized as sharing the same biological properties. The basic names of these heterocyclic compounds differ, thus the literature search for these various species will be divergent. The rings are patentably distinct and a reference against Group I would not be a reference against Group IV.

Should Applicants traverse the restriction requirement on the grounds that the different groups are not patentably distinguishable, Applicants should identify such evidence now of record or submit any such evidence that shows the groups to be obvious variants. Such evidence may be used in a rejection under 35 USC 103(a) if the Examiner finds any of the Groups unpatentable over the prior art.

4. Inventions I-X and XI-XXIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case both are true. Firstly, there are many treatments of asthma, for

example, distinct from use of Applicants' compounds. Secondly, Applicants admit their compounds have at least twenty-two different contemplated uses.


5. IF Applicants elect the compounds of Group X, then they must also elect a species of compound that binds to MMP-13 for purposes of classification and examination. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

8. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The FAX number for before final amendments is (703) 872-9306. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, you can reach the Examiner's supervisor, Mukund Shah at (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.


Thomas McKenzie, Ph.D.
Patent Examiner
Art Unit 1624

TCMcK
June 28, 2003